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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/392,934	10/28/96	SMITH	R 01-3033

HM12/0203

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EXAMINER	
SCHWADRON, R	
ART UNIT	**PAPER NUMBER**
1644	35

DATE MAILED: 02/03/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applic[illegible](s)
08/392,934	Smith et al.
Examiner	**Group Art Unit**
Ron Schwadron, Ph.D.	1644

☐ Responsive to communication(s) filed on _____ .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-36* is/are pending in the application.

Of the above, claim(s) *2-30, 32, 33, and 35* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1, 31, 34, and 36* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. Applicant's election with traverse Group I, claims 1,31,34 and 36 in Paper No.31 is acknowledged. The traversal is on the ground(s) that are stated in said paper. This is not found persuasive because of the following reasons . Regarding applicants arguments, the PTO currently interprets "consisting essentially" as recited in the instant claims as encompassing the intact protein from which the peptide recited in the claims was derived. Said molecule was known in the art. In addition, the claims encompass the fourth peptide recited in the claims with any five amino acids attached to the N-terminal end. The antibodies of Group III bind said peptide. However, said antibodies are known in the art. Sculley et al. (WO 91/08224, cited on IDS enclosed with the instant application) teaches the peptide epitope AHARDK and antibodies which bind said epitope (see entire document). Said epitope is encompassed by the fourth peptide recited in the claims (eg. any five amino acids attached to K at N-terminal). Therefore, the antibodies taught by Sculley et al. anticipate the invention of Group III. Therefore, the technical feature linking the inventions of Groups I-VII does not constitute a special technical feature a defined by PCT rule 13.2, as it does not define a contribution over the prior art.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 2-30,32,33,35 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected inventions, the requirement having been traversed in Paper No. 31 .

3. Applicant's election of the peptide species (XaaETFTETWNRFITHTEXaa)n in Paper No. 33 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

4. Claims 1,31,34,36 are under consideration

5. It is suggested that in order to avoid potential confusion that the brackets recited in claim 36 be changed to parentheses. Brackets are generally used in an amended claim to indicate deleted subject matter.

6. The drawings filed in the instant application were not objected to by the draftsperson as per the enclosed PTO 948.

7. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because the oath discloses that 08/392934 was filed on 9/15/93. However, the filing date of the instant application is 10/28/96. In addition, if applicant desires to have priority to parent application PCT 93/08699, then priority to said application should be claimed under 35 U.S.C. 120.

8. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

9. References cited on multiple filed IDSs were only considered on one IDS (eg. US Patent 4879213 was cited on three different submitted IDSs).

10. Claim 31 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification does not disclose how to use the instant invention for the therapy of EBV related disease in vivo in humans. The claimed pharmaceutical composition is disclosed in the specification as used for the treatment of EBV related disease in vivo in humans. Applicant has not enabled the breadth of the claimed invention in view of the teachings of the specification because the use for the instant invention disclosed in the specification is the in vivo treatment of disease in humans. The state of the art is such that is unpredictable in the absence of appropriate data as to how the instant invention could be used for the treatment of disease in vivo in humans. The specification provides no working examples indicating that the method of the instant invention can be used for the treatment of human disease. Jackman et al. teaches that there is currently no available vaccine for treatment of EBV related disease in humans (see abstract). Jackman et al. teach

that in order to establish whether an EBV related protein would even be tested to determine that said protein could be used to treat EBV related disease in humans, that it was necessary to obtain appropriate in vivo data in an appropriate in vivo preclinical model such as cottontop tamarins (eg. see page 660, second column). The specification supplies no in vivo data in any animal model indicating that the claimed invention can be used to treat EBV related disease in humans. It appears that undue experimentation would be required of one skilled in the art to practice the instant invention using the teaching of the specification. See In re Wands 8 USPQ2d 1400(CAFC 1988).

11. Regarding the application of prior art, the PTO currently interprets "consisting essentially" as recited in the instant claims as encompassing the intact protein from which the peptide recited in the claims was derived. Regarding priority for the instant application as pertains to prior art, in the absence of a priority claim to PCT 93/08699, the instant application is only entitled to priority to the filing date of the instant application (08/392934) as per the declaration in the instant application. This issue can be addressed by submission of a new declaration claiming priority to PCT 93/08699.

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (f) he did not himself invent the subject matter sought to be patented.

13. Claims 1,31,34,36 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

WO 94/06470 establishes that three of the four individuals disclosed as inventors of the claimed invention actually invented the claimed invention (see Inventors, page 1 and claims 1,31,34,36). The instant application has a different inventive entity (eg. four inventors). Therefore, WO 94/06470 establishes that the claimed invention was not invented by the inventors of the instant application.

14. Claims 1,31,34,36 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith et al. WO 94/06470.

Smith et al. teach the claimed invention (see claims 1,31,34,36).

15. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Pothen et al.

Pothen et al. teach the peptide of claim 1 (see Table 1).

16. Claims 1 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Pearson et al.

Pearson et al. teach the amino acid sequence of the EBV EA-R 17kDa antigen(see figure 2, page 1540). This is the intact protein from which the peptide recited in the claims is derived.

17. Claims 1,31,34,36 are rejected under 35 U.S.C. 102(b) as being anticipated by Pothen et al. (1991).

Pothen et al. the EBV EA-R 17kDa antigen(see figure 2, page 1540). This is the intact protein from which the peptide recited in the claims is derived (see page 657, column 1). Pothen et al. teach said peptide in a composition with a pharmacological carrier (eg. tissue culture media, see page 657, column 1). Pothen et al. teach the ingredients of the claimed kit (see page 657, column 1).

18. No claim is allowed.

19. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP ~~1800~~ 1600